



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Application of: James P. Elia )  
Serial No.: 09/064,000 ) Group Art Unit: 1646  
Filed: April 21, 1998 ) Examiner: Elizabeth C. Kemmerer, Ph.D.  
For: METHOD FOR GROWTH )  
OF SOFT TISSUE )

**SUPPLEMENTAL DECLARATION OF RICHARD HEUSER, M.D.**

I Richard Heuser declare as follows:

1. I have offices at 500 West Thomas Road, Suite 900, Phoenix, Arizona 85013.
2. This Supplemental Declaration is submitted in addition to my previous Declaration, dated November 11, 2004. No changes are made to my previous Declaration.
3. My Curriculum Vitae is attached as Exhibit A to my Declaration of November 11, 2004.
4. It is my understanding that the Examiner in charge of the above-identified patent application is also in the Examiner in charge of co-pending patent application Serial No. 09/794,456. In an Advisory Action dated November 26, 2004, for aforesaid Serial No. 09/794456, the Examiner questioned my qualification to render my opinions in my previous Declarations filed in such application. It is my further understanding that the Examiner reviewed my U.S. Patent No.

6,190,379 and did not find mention of delivery of any substance to the myocardium nor the word "cell." Also, the Examiner questioned my role in the cell delivery portion of Bioheart's laboratory and clinical trials using skeletal muscle cultured and modified. For the instant application, I provide the following information to respond to the Examiner's questions.

5. Regarding, U.S. Patent No. 6,190,379, the following is stated in Paragraph 3 of my Declaration:

In my U.S. Patent No. 6,190,379 entitled "Hot Tip Catheter," I developed a technique to deliver radiofrequency (PMR). In the full embodiment of the patent, I discuss delivery of protein and/or muscle cells in the myocardium using the inventive technique.

By the above statement, I meant that the device shown in the patent has been used for the delivery of protein and/or muscle cells to the myocardium. At a presentation at the Angiogenesis Meeting in 1999 in Washington, D.C., we described this use of growth factors in a pig model with the development of neo vascularization. Moreover, I have had discussions with Bioheart regarding the use of my U.S. Patent No. 6,190,379 for delivery of cells.

Regarding my work at Bioheart, the following is stated in my Declaration:

I have been involved as a member of the scientific advisory board with the world leader in cardiomyocyte regeneration, Bioheart, Miami Lakes, Florida. This company has been involved with laboratory and clinical trials using skeletal muscle cultured and modified. The sample is then delivered into the myocardium via a surgical or catheter approach.

To provide further information regarding the Examiner's questioning my involvement with Bioheart, I am a Scientific Advisory Board Member and in such role advise Bioheart throughout its pre-clinical and clinical work involving the

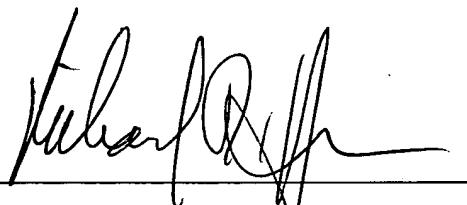
delivery of skeletal muscle cells into the myocardium. I am also an investigator with Bioheart's Phase 3 clinical trials in the United States. Such trials have not yet commenced.

6. Declarant states that the above opinion was reached independently.

Declarant understands that (1) any willful false statements and the like made herein are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any patent issuing thereon, and (2) that all statements made of Declarant's own knowledge are true and that all statements made on information and belief are believed to be true.

Further Declarant sayeth not.

Date: 2/16/05



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Richard Heuser, M.D., F.A.C.C., F.A.C.P.